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#### **REMARKS**

Claims 40-52 and 54-77 are pending in the application.

Herein claims 40, 41, 43, 45, 47-50, 54, 60, 63-65, 68, 70-72 and 74 are amended, no claims are canceled, and no new claims are added.

The amendments submitted herewith are intended to place the application in condition for allowance, do not raise any new issues nor require additional searching by the Examiner.

Applicants respectfully request entry and favorable consideration of the present reply to final Office Action.

# **OBJECTION TO THE DRAWINGS**

The Examiner objected to the drawings because it's alleged that the first and second environment with respect to the housing is claimed at claims 63-66 but not depicted in the drawings. However, Applicants respectfully disagree in that the following passage from the application as filed clearly provides support for the inherent notion that the housing has a "first environment within the housing" and a "second environment outside the housing."

Figure 11 illustrates various cross-sectional views of a molded connector 90 comprising a molded housing 84 enclosing a plurality of electrical contact strips 72. The housing 84 encloses a portion of the contact strips 72 and electrically insulates them. Exposed areas of the contact strips 72 provide a first contact surface 76, a second or middle contact surface 78 and a third contact surface 80 for each contact strip 72. Channels 86 within the housing 84 provide pathways for electrical components, such as wires, to be connected to the middle contact surfaces 78, while physically separated from the other contact surfaces, such as the third contact surfaces 80. (page 8, lines 23-31; emphasis added.)

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In addition, Applicants suggest that the Examiner review FIGS. 8A, 8B, 9A, and 9B. Applicants suggest that the passage and drawings (and method claims) originally filed clearly depict the metallic insert (see perspective views at FIGS. 8A and 8B) that is inserted into the housing, then the scribed tab is broken and the housing thus presents multiple wire-bonding pads for later permanent attachment (e.g., manually or automatically welded, soldered, laser bonded, etc.) to elongated conductor(s). The foregoing notwithstanding, Applicants herewith amend claims 63-65 to modify the use of the term "environments" to —sides—because the specification clearly supports the claim term and in an attempt to advance the prosecution of the application to ultimate issuance as U.S. Letters Patent. Thus, the objection to the drawings has been traversed and should be withdrawn.

### **CLAIM OBJECTION**

Claim 77 stands objected to because the phrase "the plurality of apertures" was not introduced with proper antecedent basis (citing claim 77, at line 3). However, Applicants assert that proper antecedent basis is indeed present for the element recited at line 3; namely, in claim 77 (at line 2) the element is introduced as "a plurality of apertures...". Thus, since this objection lacks merit no further response is required and the ground of objection withdrawn.

## CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 59 and 71 are rejected under 35 U.S.C.§112, second paragraph.

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Both claims are allegedly because of a perceived inconsistency within the claims. However, as previously stated, Applicants have employed open-ended transitional phrases with the claims. Applicants suggest that the claims cover any apparatus having each element recited and any other element or feature. Accordingly, Applicants decline to "clarify what subject matter the claims are intended to be drawn to." Instead, Applicants simply note that, generally speaking, the independent claims are drawn to multi-pin wire-bonding components for implantable medical devices and some of the dependent (narrower) claims are drawn to such components coupled to specific types of implantable medical devices.

### CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 40-48, 50-52, 54, 56 and 57 are rejected as being anticipated by U.S. Pat. No. 6,059,601 to Hirai ("Hirai"). Applicants respectfully traverse the rejections as enumerated hereinbelow.

"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id.

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. <u>Lewmar Marine</u>, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without

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disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

Herewith Applicants have amended the rejected independent claims (i.e., claims 40 and 45) herein to distinguish Hirai. As repeatedly noted by the Court of Appeals for the Federal Circuit, Applicants need only show a single difference between the claimed combination and Hirai in order to traverse the instant ground of rejection. If independent claims 40 and 45 can be shown to be novel over Hirai, then the remaining rejected dependent claims are novel over Hirai too. In this regard, Applicants respectfully suggest that Hirai fails to depict or disclose a metallic insert having a manually removable tab attached to the plurality of wire contact pads thus providing temporary common electrical communication among the tab and the pads.

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### CLAIM REJECTIONS UNDER 35 U.S.C. §103

In the Office Action, claims 49, 58-65, 67-75 and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirai. According to the Examiner, Hirai discloses substantially the claimed invention except for the component being a component of an implantable medical device (IMD). The Examiner concluded, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the structure of Hirai as a component of different electrical devices, such as an IMD.

Also, claims 55 and 66 stand rejected as being unpatentable over Hirai in view of Damaschke et al. (the '884 patent); claim 76 stands rejected as being unpatentable over Hirai in view of Hawkins et al. (the '089 patent); and claims 60-69 stand rejected as being unpatentable over Hirai in view of Urushibata et al. (the '650 patent).

First of all, Applicants herewith amend the claims to place them in condition for allowance. Second of all, Applicants suggest that the primary (and for some claims sole) reference relied upon by the Examiner does not devote any text or drawings to the notion of a means of permanently coupling wires (e.g., welding, soldering, laser bonding, etc.). In the present invention, this compact assembly presents multiple bonding / contact pads to distal portions of elongated conductors. The removable multiple pin assembly of Hirai simply could not be used in a compact IMD. To use a "press-pinching connector" (part of the title of Hirai) in a potentially life-saving IMD would present an unacceptable risk. As is known in the art, any deployable medical electrical leads coupled to an IMD are not only friction-fit with multiple redundant

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gaskets and seals, they are mechanically screwed together as well. While the foregoing does not form the basis for addressing the rejection, Applicants would like the Examiner to at least recognize the medical needs the application addresses.

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In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a prima facie case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A prima facie case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). In the present application, no such showing has been made with respect to Hirai.

In the case of <u>in re Lee</u>, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." Id. at 1434. Determination of patentability must be based on evidence, <u>id.</u> at 1434. Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's

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obligation to make an evidentiary record. <u>Id.</u> at 1434-35; <u>In re Demblczak</u>, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. <u>In re Lee</u>, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. <u>See id.</u> at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims claims 49, 58-65, 67-75 and 77; 55 and 66; 76; and 60-69

### C. Conclusion

Applicant submits that the pending claims are patentably distinct over the cited references, as applied singly and in combination, and that all claims are in condition for allowance. Accordingly, Applicants requests that a Notice of Allowance be issued in due course.

By:

Respectfully submitted,

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